### REMARKS

Reconsideration is requested.

The specification has been amended to include the attached Sequence Listing.

The attached paper and computer readable copies of the Sequence Listing are the same. No new matter has been added.

A copy of the Notification of Defective Response dated January 9, 2007 is attached. A copy of the "CRF Problem Report" attached to the Notification of Defective Response dated January 9, 2007 is attached.

The undersigned notes that the CRF copy of the Sequence Listing submitted on September 19, 2006 in response to the Notification of August 24, 2006 is, with respect to the "invention title, docket number, or applicant(s)", the same as the originally-filed Sequence Listing. The CRF filed September 19, 2006 therefore is not believed to be the "Wrong file saved to CRF" as indicated by the Patent Office in the "CRF Problem Report" received with the Notification of Defective Response dated January 9, 2007, and which was apparently the basis of the Notification. The attached Sequence Listing includes a revision of the objected-to information.

A review of the PTO IFW reveals a Notification of Defective Response dated November 17, 2006 (document no. 0C000000021266049) and RAW SEQUENCE LISTING ERROR REPORT from processing by STIC on September 22, 2006. A copy of these papers is attached. The undersigned has not received these papers prior to February 6, 2007 when they were obtained by the undersigned from a review of the PTO IFW.

Attached is a copy of the undersigned's docket sheet from December 17, 2006, where a one month action allegedly mailed November 17, 2006, would have been docketed, as evidence of non-receipt of the Notification of Defective Response dated November 17, 2006 (document no. 0C000000021266049) and RAW SEQUENCE LISTING ERROR REPORT from processing by STIC on September 22, 2006.

The undersigned affirms and attests that a search of the file jacket and docket records indicates that the Notification of Defective Response dated November 17, 2006 (document no. 0C000000021266049) and RAW SEQUENCE LISTING ERROR REPORT from processing by STIC on September 22, 2006 were not received prior to the February 6, 2007 discovery of same by the undersigned in reviewing the PTO IFW.

The attached Sequence Listing includes revision believed to be corrective of the errors indicated in the RAW SEQUENCE LISTING ERROR REPORT from processing by STIC on September 22, 2006.

The present Amendment and attached are believed to be completely responsive to the Notification of Defective Response dated January 9, 2007. The Office is requested to contact the undersigned in the event anything further is required in this regard.

NAKANO et al. Appl. No. 10/575,253 February 7, 2007

Respectfully submitted,

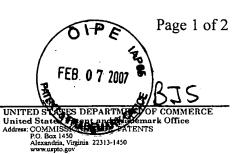
# **NIXON & VANDERHYE P.C.**

| By: | /B. J. Sadoff/  |  |
|-----|-----------------|--|
| _   | B. J. Sadoff    |  |
|     | Reg. No. 36,663 |  |

BJS:

901 North Glebe Road, 11th Floor

Arlington, VA 22203-1808 Telephone: (703) 816-4000 Facsimile: (703) 816-4100



U.S. APPLICATION NUMBER NO. FIRST NAMED APPLICANT ATTY. DOCKET-NO.

10/575,253 Ryosuke Nakano 249-423 

INTERNATIONAL APPLICATION NO.

PCT/JP04/15315

1.A. FILING DATE PRIORITY DATE

SON & VANDERHYE. PC 10/08/2004 10/09/2003.

23117 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203

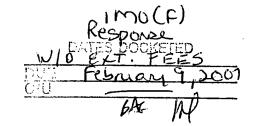
CONFIRMATION NO. 9644
371 FORMALITIES LETTER
\*OC000000021899142\*

Date Mailed: 01/09/2007

### NOTIFICATION OF DEFECTIVE RESPONSE

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495)

- Priority Document
- Copy of the International Application filed on 04/10/2006
- Copy of the International Search Report filed on 04/10/2006
- Preliminary Amendments filed on 04/10/2006
- Information Disclosure Statements filed on 04/10/2006
- Biochemical Sequence Diskette filed on 09/19/2006
- Oath or Declaration filed on 04/10/2006
- Biochemical Sequence Listing filed on 09/19/2006
- Request for Immediate Examination filed on 04/10/2006
- Copy of references cited in ISR filed on 04/10/2006
- U.S. Basic National Fees filed on 04/10/2006
- Priority Documents filed on 04/10/2006
- Specification filed on 04/10/2006
- Claims filed on 04/10/2006
- Abstracts filed on 04/10/2006
- Drawings filed on 04/10/2006
- Paper nucleotide sequence listings filed on 04/10/2006



Applicant's response filed 09/19/2006 is hereby acknowledged. The following requirements set forth in the NOTIFICATION of MISSING REQUIREMENTS mailed 08/24/2006 have not been completed.

A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of
the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as
indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a
substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content
of the sequence listing information recorded in computer readable form is identical to the written (on paper
or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR
1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

• The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d). Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. <a href="https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html">https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html</a>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

MAMIE P PERSON

Telephone: (703) 308-9140 EXT 227

### PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY, DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/575,253                  | PCT/JP04/15315                | 249-423          |

FORM PCT/DO/EO/916 (371 Formalities Notice)

## STIC Biotechnology Systems Branch

# **CRF Problem Report**

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) experienced a problem when processing the following computer readable form (CRF):

| Application Serial Number: 10/17/03/5 Filing Date:                              |
|---|
| Date Processed by STIC: 4/25/06   |
| STIC Contact: Mark Spencer: Telephone: 571-272-2510; Fax: 571-273-0221          |
| Nature of CRF Problem:  |
| (circle one) Damaged or Unreadable (for Unreadable, see attached)               |
| Plank (no files on CRF) (see attached)  |
| Empty file (filename present, but no bytes in file) (see attached)              |
| Wrong file saved to CRF (invention title, docket number, or applicant(s) do not |
| match those in official application) (see attached)                             |
| Not saved in ASCII text   |
| Sequence Listing was embedded in the file. According to Sequence Rules,         |
| submitted file should only be the Sequence Listing.                             |
| Did not contain a Sequence Listing. (see attached sample)                       |
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| PLEASE USE THE CHECKER VERSION 4.3.1 PROGRAM TO REDUCE ERRO                     |
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PLEASE USE THE CHECKER VERSION 4.3.1 PROGRAM TO REDUCE ERRORS. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

- 1. EFS-Bio (<a href="http://www.uspto.gov/ebc/efs/downloads/documents.htm">http://www.uspto.gov/ebc/efs/downloads/documents.htm</a>, EFS Submission User Manual ePAVE)
- 2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
- 3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):
  U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street,
  Alexandria, VA 22314

Revised 08/30/05

( ) Ample or submitted MIE)

10/575,253

-SEQUENCE LISTING

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<120 Protein-free medium adapted FUT8 knouck out cells

<130> 11620WO1

√150> JP2003-3501<del>66</del>

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<160> 32

(See attachments)

Day : Monday Date: 4/24/2006

Time: 14:36:45

# PALM INTRANET

| Application Number Information                |   |
|---|---|
| Application Number: 10/575253  Assignments    | Examiner Number: 00000 /                            |
| Filing or 371(c) Date: 00/00/0000             | Group Art Unit: 0000 / IFW IMAGE /                  |
| Effective Date: 04/10/2006                    | Class/Subclass: /.                                  |
| Application Received: 04/10/2006              | Lost Case: NO                                       |
| Patent Number:                                | Interference Number:                                |
| Issue Date: 00/00/0000                        | Unmatched Petition: NO                              |
| Date of Abandonment: 00/00/0000               | L&R Code: Secrecy Code:                             |
| Attorney Docket Number 249423                 | Third Level Review: NO Secrecy Order: NO            |
| Status: 19 /APPLICATION UNDERGOING PROCESSING | G PREEXAM Status Date: 04/18/2006                   |
| COMMITTEE CO.                                 | Oral Hearing: NO                                    |
| Title of Invention: GENOMICALLY MODI          | FIED CELL NEUTRALIZED TO SERUM-FREE                 |
| Bar Code PALM Location Location Date C        | harge to Loc Charge to Name Employee Name Location  |
| Appln Contents Petition Info                  | Agent Info: - Continuity Data: Foreign Data: - Fig. |
| Search Another: Application#                  | Search or Patent# Search                            |
| PCT / /                                       | Search or PG PUBS # Search                          |
| Attorney Docket #                             | Search  |
| Bar Code #                                    | Search  |

To go back use Back button on your browser toolbar.

Back to PALM | ASSIGNMENT | OASIS | Home page

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| PAL          | INTRANET |

Day: Tuesday Date: 4/25/2006

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| Priority#  | Date             | Country                    |
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| Attorney Docket #  |                  | arch                       |
| Bar Code #   | Search           |                            |

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December 17, 2506

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### JNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1500 Alexandra, Vignin 27313-1450

ATTY. DOCKET NO. U.S. APPLICATION NUMBER NO. FIRST NAMED APPLICANT 249-423

10/575,253 Ryosuke Nakano

INTERNATIONAL APPLICATION NO.

PCT/JP04/15315

PRIORITY DATE I.A. FILING DATE

10/08/2004

OC000000021266049\*

10/09/2003

**CONFIRMATION NO. 9644** 371 FORMALITIES LETTER 

Date Mailed: 11/17/2006

RLINGTON, VA 22203

ON & VANDERHYE. PC

NORTH GLEBE ROAD, 11TH FLOOR

### NOTIFICATION OF DEFECTIVE RESPONSE

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495)

- Priority Document
- Copy of the International Application filed on 04/10/2006
- Copy of the International Search Report filed on 04/10/2006
- Preliminary Amendments filed on 04/10/2006
- Information Disclosure Statements filed on 04/10/2006
- Biochemical Sequence Diskette filed on 09/19/2006
- Oath or Declaration filed on 04/10/2006
- Biochemical Sequence Listing filed on 04/10/2006
- Request for Immediate Examination filed on 04/10/2006
- Copy of references cited in ISR filed on 04/10/2006
- U.S. Basic National Fees filed on 04/10/2006
- Priority Documents filed on 04/10/2006
- Specification filed on 04/10/2006
- Claims filed on 04/10/2006
- Abstracts filed on 04/10/2006
- Drawings filed on 04/10/2006
- Paper nucleotide sequence listings filed on 04/10/2006

Applicant's response filed 09/19/2006 is hereby acknowledged. The following requirements set forth in the NOTIFICATION of MISSING REQUIREMENTS mailed 08/24/2006 have not been completed.

 The paper or compact disc copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e). Applicant must provide a substitute paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application OR a substitute computer readable form (CRF) copy of the "Sequence Listing". These two items must be the same. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR

- 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d). Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <a href="http://www.uspto.gov/ebc.">http://www.uspto.gov/ebc.</a>

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

MAMIE P PERSON

Telephone: (703) 308-9140 EXT 227

### PART 2 - OFFICE COPY

| _ | U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|---|-----------------------------|-------------------------------|------------------|
|   | 10/575.253                  | РСТ/JP04/15315                | . 249-423        |

FORM PCT/DO/EO/916 (371 Formalities Notice)

# STIC Biotechnology Systems Branch

# RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/575, 253 A
Source: 1FUO
Date Processed by STIC: 19/22/2006

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER VERSION 4.4.0 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

- 1. EFS-Bio (<a href="http://www.uspto.gov/ebc/efs/downloads/documents.htm">http://www.uspto.gov/ebc/efs/downloads/documents.htm</a>, EFS Submission User Manual ePAVE)
- 2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
- Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05):
   U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/10/06



**IFWO** 

RAW SEQUENCE LISTING DATE: 09/22/2006
PATENT APPLICATION: US/10/575,253A TIME: 09:35:33

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3 <110> APPLICANT: KYOWA HAKKO KOGYO CO., LTD.

Output Set: N:\CRF4\09222006\J575253A.raw

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                                                           Does Not Comply
13 <151> PRIOR FILING DATE: 2004-10-08
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16 <151> PRIOR FILING DATE: 2003-10-09
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9/22/2006

RAW SECUENCE LISTING DATE: 09/22/2006 TIME: 09:35:33 PATENT APPLICATION: US/10/575,253A

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the Accession date.
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187 aagcctagag aaatgattct tgtcttaagg gcaccatttc gctctcccac cgtaaagcgc 600
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VERIFICATION SUMMARY

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